UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA, Plaintiff, v. RX DEPOT, INC. and RX OF CANADA, LLC, corporations, and CARL MOORE and DAVID PEOPLES, individuals, Defendants.	NO. 03-CV-616-EA

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Phil Lombardi, Clerk
U.S. DISTRICT COURT

PLAINTIFF'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

The United States of America, plaintiff, by and through its undersigned attorneys, respectfully submits its Proposed Findings of Fact and Conclusions of Law. Plaintiff also resubmits for the Court's convenience the Proposed Order of Preliminary Injunction included with its initial pleadings.[1]

I. PROPOSED FINDINGS OF FACT

Procedural History

1. The government instituted this suit on September 11, 2003, by filing a Complaint and a Motion for a Preliminary Injunction. The government's Complaint alleged violations by

[1]Consistent with the Court's inherent authority to order equitable relief in civil cases, at the permanent injunction stage the United States will ask the Court to order the defendants to provide restitution to customers who received drugs that violate the Act.

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defendants of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. 331(d) and 331(t).

2. On September 15, 2003, the Court held a status hearing conference and set a date for an evidentiary hearing on the government's motion.

3. Defendants filed a Response on October 6, 2003, wherein they requested their own preliminary injunction against the government's attempt to enforce the FDCA. Defendants filed an Answer on October 8, 2003, requesting again that the Court enjoin FDA "from applying its regulations in a discriminatory manner."

4. On October 8 and 9, 2003, the Court heard evidence relating to both preliminary injunction motions. The government and the defendants presented witnesses and exhibits. All of the government's exhibits were accepted by the Court without objection by the defendants.

The Defendants

5. Defendant Rx Depot, Inc. ("Rx Depot"), was incorporated under the laws of the State of Nevada on December 2, 2002, and does business at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court. Appendix to Gov't. Memorandum in Support of Plaintiff's Motion for Preliminary Injunction ("App.") Ex. A, Tab 1.

6. Defendant Rx of Canada, LLC ("Rx Canada"), is a related U.S. entity incorporated in Nevada. Rx Canada is owned by defendant Carl Moore's son, Joe-Max Moore. App. Ex. A, Tab 3.

7. Rx Canada's website, www.rxofcanada.net, is substantially similar to Rx Depot's website, www.rxdepot.com. On the Rx Canada website, links to many purported Rx Canada store locations are actually links to Rx Depot stores, including some stores located in the Northern District of Oklahoma. Similarly, links to some purported Rx Depot locations on the Rx Depot website actually lead to contact information for Rx Canada stores. Transcript of Proceedings, October 8 & 9 ("Trans.") at 66-69; Government's Preliminary Injunction Hearing Ex. ("Gov't. Ex.") 11-12.

8. Defendant Carl Moore, an individual, is the President/Director of Rx Depot and a member of its Board of Directors. He has overall responsibility for, and authority over, all operations of the corporation, including the sales arrangements involving ordering, purchasing, and shipment of prescription drugs from Canada. He performs these activities at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court. App. Ex. A, Tab 1; Gov't. Ex. 6; Trans. at 50.

9. Defendant David Peoples, an individual, is the Secretary of Rx Depot. He is responsible for receiving and

processing orders for Rx Depot. He performs these activities at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court. App. Ex. A Tab 1; Gov't. Ex. 6.

10. Defendants Carl Moore, David Peoples, Rx Depot, and Rx Canada (collectively, "defendants" or "Rx Depot") operate approximately 85 Rx Depot/Rx Canada stores located throughout the United States, which serve about 800 customers each day. Trans. at 188-89.

Operation of Rx Depot/Rx Canada

11. Each Rx Depot/Rx Canada location has one or two employees who accept prescriptions from U.S. customers. Customers also are asked to fill out a medical history form and other forms provided by Rx Depot. Customers can deliver these documents to defendants' stores in person, or can mail or fax to the nearest Rx Depot/Rx Canada store. Trans. at 20-24, 44-46, 48, 51-52; Gov't. Ex. 2, 6, 11-12.

12. Once an Rx Depot/Rx Canada customer has submitted the required forms and prescription to defendants, defendants or the customer then faxes the papers and the customer's credit card information to a cooperating pharmacy in Canada. A Canadian doctor rewrites the prescription, and the Canadian pharmacy fills the prescription, bills the U.S. customer's credit card, and mails the prescription drugs directly to the U.S. customer. Trans. at 22, 45-46, 48, 51-52; Gov't. Ex. 6.

13. Defendants receive a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. The defendants also receive commissions for refill orders, which generally are arranged directly between customers and the Canadian pharmacies. Trans. at 189-90; Gov't. Ex. 6.

14. Defendants are essentially commissioned sales agents for Canadian pharmacies. Trans. at 191.

15. An Oklahoma state court recently ordered the defendants' stores in Oklahoma to close after finding that the defendants acted as storefronts for Canadian pharmacies and, as such, were operating as unlicensed pharmacies. Trans. at 190-191; Gov't. Ex. 25.

16. Defendants admit in their Answer to the government's Complaint that they are engaged in the business of causing the shipment of U.S.-manufactured and unapproved, foreign-manufactured prescription drugs from Canadian pharmacies to U.S. citizens. See Defendants' Answer and Counterclaims, ¶6.

17. The defendants actively solicit other individuals to open "affiliate" Rx Depot/Rx Canada stores by distributing promotional materials that describe their business practices and the potential profits to be made from opening a franchise. Defendants estimate that an affiliate would receive an average 9% commission on each sale of Canadian prescription drugs, about $24.75. The net commissions for an affiliate in the first year

would be an estimated $141,570, according to the defendants. Gov't. Ex. 1. The defendants' affiliate "Agreement" also states, however, that the service "may at some date be determined to be unlawful or otherwise prohibited." Id. at 29.

Prescription Drugs from Foreign Countries

18. Unapproved prescription drugs, and drugs imported from foreign countries by someone other than the U.S. manufacturer, do not have the same assurance of safety and efficacy as drugs regulated by FDA. Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States. For instance, the drugs may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs may have been held under uncertain storage conditions, and therefore be outdated or subpotent. Trans. at 127-28, 141-42, 144; App. Ex. B (McGinnis Decl.) at ¶¶ 11, 14.

19. Prescription drugs obtained through Rx Depot frequently are dispensed in greater quantities than are requested by the prescribing physician. Rx Depot advertises the availability of, and causes the importation of, preset quantities of drugs and dispenses these preset quantities regardless of the quantity of the drug the patient's U.S. physician prescribed and without directions to take the drug for only the number of days

prescribed by the U.S. physician. Trans. at 46-47, 62-63, 97-98; Gov't. Ex. 10, 11-12.

20. American patients could, therefore, take a drug for many days more than their physicians intend without supervision. This practice can be dangerous in instances where drugs have potentially life-threatening side effects with continued use. Trans. at 98; App. Ex. C (Katz Decl.) at ¶ 14.

21. Prescription drugs obtained through Rx Depot also do not contain the FDA-approved patient package inserts included with certain prescription drugs in the United States. Nor are prescription drugs obtained through Rx Depot shipped in FDA-approved unit-of-use packaging. This type of packaging is used in the United States to help ensure that certain drugs received by customers arrive in designated dosages with the approved patient package insert. Trans. at 98-104; Gov't. Ex. 10, p.16-17, Ex. 18.

Undercover Purchases by FDA

22. In May 2003, FDA made an undercover purchase through Rx Depot. An FDA investigator in Maryland downloaded the necessary Rx Depot order forms and related paperwork from the Rx Depot website and filled them out as though he were a patient. The investigator also prepared a prescription for 60 pills, to be taken twice a day for 30 days, of the FDA-approved prescription drug Serzone, which is used to treat depression. The

prescription allowed one refill. On the Rx Depot form, the investigator ordered a 100-pill package offered on the Rx Depot website rather than the 60 pills indicated on the prescription. Trans. at 46-47, 62-63; Gov't. Ex. 9.

23. On May 10, 2003, a second FDA investigator in Oklahoma took the order forms and prescription to an Rx Depot store located at 5801 N. May, Suite 101, Oklahoma City, Oklahoma. The investigator provided the order forms and prescription to the store manager. The Rx Depot manager accepted the paperwork and faxed or mailed the information to a Canadian pharmacy. The manager did not indicate that ordering a greater number of pills than what the prescription called for would be a problem. In fact, the manager stated that drugs obtained through Rx Depot usually came in packages of 100 pills. Trans. at 43-48; Gov't. Ex. 8-9.

24. In late May 2003, FDA received a package from Pharmacy North, Inc., in Winnipeg, Manitoba, Canada. The package contained 99 pills (and was labeled as containing 100) of a foreign-manufactured version of Serzone, known as APO-Nefazodone. The labeling provided with the APO-Nefazodone did not direct the patient to take the drug for 30 days or for any other specified period of time. Trans. at 64-65; Gov't. Ex. 10.

25. APO-Nefazodone is not generally recognized among qualified experts as safe and effective for use under the

conditions prescribed, recommended, or suggested in its labeling. Trans. at 93; App. Ex. C (Katz Decl.) at ¶¶ 8-11.

26. APO-Nefazodone does not have in effect FDA approval of any new drug or abbreviated new drug applications filed pursuant to 21 U.S.C. §§ 355(b) or (j). It does not have in effect a valid exemption from such approval requirements under 21 U.S.C. § 355(I). Trans. at 94; App. Ex. D (Richman Decl.) at ¶ 4.

27. In the United States, Serzone is sold in "unit-of-use packaging" designed to ensure, as much as possible, that the patient receives a designated dose with an FDA-approved patient package insert. The insert includes important information regarding the drug, such as warnings related to potentially serious side effects. One potential side effect of Serzone, and generic versions of Serzone such as APO-Nefazodone, involves increased risk of serious liver damage. Trans. at 95, 99, 103; Gov't. Ex. 17-18.

28. The labeling provided by the Canadian pharmacy with the APO-Nefazodone included fewer and far less descriptive warnings regarding potential side effects than the FDA-approved patient package insert for Serzone. For example, the Canadian instructions do not specify some of the liver failure symptoms listed on the Serzone insert, do not mention drugs that should be avoided when taking Nefazodone, and do not convey the sense of urgency reflected in the Serzone insert. These substandard

instructions could increase the risk of adverse events, including life-threatening liver failure. Trans. at 95, 101-02, 120-21; Gov't. Ex. 10, 18.

29. Patient safety also can be compromised when a pharmacy provides more pills than the number prescribed by the doctor. In the case of antidepressants such as Serzone and APO-Nefazodone, potential problems associated with taking a longer-than-prescribed course of medication include increased risk for serious liver problems. Pharmacies in the United States typically do not supply patients with refills until their previous prescriptions are nearly completed. Trans. at 97-98, 106.

30. In late July 2003, an FDA investigator made a second undercover purchase by faxing an order for Sporanox to Rx Depot's Tulsa, Oklahoma, location. Trans. at 20-21; Gov't. Ex. 2-3.

31. Sporanox is an FDA-approved prescription drug manufactured in Puerto Rico by Janssen Pharmaceutica, Inc., that is used to treat nail fungal infections. Trans. at 20, 24, 38; Gov't. Ex. 5.

32. In early August 2003, FDA received the Sporanox order from Pharmacy North, Inc., in Winnipeg, Manitoba, Canada. The Sporanox was shipped into the United States by a party other than the manufacturer. Trans. at 22-23; Gov't. Ex. 4.

33. The drug products purchased by FDA through undercover buys represent just two of the hundreds of prescription drugs advertised on the defendants' websites. Gov't. Ex. 11-12.

34. Defendant Moore admitted at the hearing that prescription drugs from Canadian pharmacies are not approved by FDA and that some of them are manufactured in the United States. Trans. at 190. Defendants' websites also state that the advertised drugs are not FDA-approved. Gov't. Ex. 11-12.

FDA Warnings to the Defendants

35. On March 21, 2003, FDA issued a Warning Letter to the Rx Depot store located at 200 S. Bloomington, Ste. E1, Lowell, Arkansas; copies of the letter were sent to defendants Moore and Peoples. The letter informed the defendants that FDA believed them to be violating 21 U.S.C. § 381(d)(1), because they caused prescription drugs manufactured in the United States to be reimported by persons other than the manufacturer of the drug. Further, the letter stated that the defendants violated 21 U.S.C. § 355 by causing unapproved new drugs to be imported into the United States. Trans. at 69-70, 187-88; Gov't. Ex. 13.

36. On May 6, 2003, the defendants responded to FDA's Warning Letter. Defendants stated that all drugs they cause to be obtained from Canadian pharmacies are "manufactured in the United States." Defendants also stated that the drugs advertised on Rx Depot's website and obtained by their customers from

Canadian pharmacies "'are not' FDA approved." Trans. at 70-71; Gov't. Ex. 14.

37. In their response to FDA's warnings, defendants did not indicate any intention to halt their illegal practices. By letter dated June 10, 2003, FDA informed the defendants that their response was inadequate. Trans. at 71; Gov't. Ex. 14-15.

38. Since receiving the FDA Warning Letter, the defendants have opened more than 50 additional Rx Depot and Rx Canada stores. Trans. at 190.

39. Defendant Moore testified at the hearing that the defendants would continue their activities unless this Court enjoins them. Trans. at 192.

40. FDA has sent numerous other Warning Letters and informational letters to operations similar to Rx Depot and individuals considering engaging in such activities. Gov't. Ex. 20. In these letters, some of which pre-date the start of the defendants' business, FDA has consistently stated to interested parties that "a U.S. pharmacy or other business virtually always violates U.S. law by importing or causing the importation of [drugs from Canadian pharmacies]." Id. at 8.

41. Any proposed Conclusion of Law more appropriately considered a Finding of Fact is submitted as such.

II. PROPOSED CONCLUSIONS OF LAW

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

2. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

3. The defendants violate 21 U.S.C. § 331 by causing the importation of prescription drugs from Canadian pharmacies.

4. APO-Nefazodone is one of the prescription drugs that the defendants cause to be imported. It is a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and a new drug under 21 U.S.C. § 321(p).

5. Defendants violate 21 U.S.C. § 331(d) each time they cause to be introduced or delivered for introduction into interstate commerce unapproved new drugs in violation of 21 U.S.C. § 355. Specifically, the defendants cause the importation of the unapproved new drugs, such as APO-Nefazodone, listed on their website.

6. Sporanox, another one of the prescription drugs the defendants cause to be imported, is manufactured in Puerto Rico. Pursuant to 21 U.S.C. § 321(a)(1), Puerto Rico is a "state" for purposes of 21 U.S.C. § 381(d)(1). Thus, Sporanox is a U.S.-manufactured drug and cannot be imported into the United States by anyone other than the drug's manufacturer.

7. Defendants violate 21 U.S.C. § 331(t) each time they cause the importation of prescription drugs in violation of 21 U.S.C. § 381(d)(1). Specifically, the defendants cause the reimportation of the U.S.-manufactured drugs, such as Sporanox, listed on their website. Reimportation of U.S.-manufactured drugs, even those approved for use in the United States, violates the FDCA, because only the manufacturer of a drug can reimport that drug into the United States. 21 U.S.C. § 381(d)(1).

Preliminary Injunction Standard

8. The United States seeks a preliminary injunction to stop defendants from further FDCA violations. Generally, an injunction may issue where the movant shows: (1) a substantial likelihood of success on the merits; (2) irreparable injury if the injunction is not granted; (3) that injury outweighs any harm the injunction will cause the opposing party; and (4) the injunction is in the public interest. O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft, 342 F.3d 1170, 1177 (10th Cir. 2003) (available at 2003 WL 22055828); SCFC ILC, Inc. v. Visa USA, Inc., 936 F.2d 1096, 1098 (10th Cir. 1991). Where an injunction would alter the status quo, a heightened standard of scrutiny normally applies. O Centro Espirita, 342 F.3d at 1177-78, n.3.

9. The overriding purpose of the FDCA is to protect the public health. United States v. An Article of Drug ...

Bacto-Unidisk, 394 U.S. 784, 798 (1969); United States v. Undetermined Quantities of Bottles ..., 22 F.3d 235, 238 (10th Cir. 1994). It is well settled that where a statute designed to protect the public authorizes injunctive relief, considerations applicable to private injunctive actions, such as irreparable injury and a balancing of the equities, are not relevant. See Hecht Co. v. Bowles, 321 U.S. 321, 331 (1944); United States v. Odessa Union Warehouse Co-op, 833 F.2d 172, 174-75 (9th Cir. 1987); United States v. City of Painesville, Ohio, 644 F.2d 1186, 1193 (6th Cir. 1981); United States v. Diapulse Corp., 457 F.2d 25, 27-28 (2d Cir. 1972). Specifically, where an injunction is authorized by statute, as here, the agency to whom the enforcement of the statute has been entrusted is not required to show irreparable harm or that its harm would outweigh the harm to defendants. Mical Communications, Inc. v. Sprint Telemedia, Inc., 1 F.3d 1031, 1035-36 (10th Cir. 1993)(citing Atchison, Topeka and Santa Fe Railway Co. v. Lennen, 640 F.2d 255, 259 (10th Cir. 1981)); Odessa Union, 833 F.2d at 175-76; Illinois Bell Telephone Co. v. Illinois Commerce Comm'n, 740 F.2d 566, 571 (7th Cir. 1984); Virgin Islands v. V.I. Paving, Inc., 714 F.2d 283, 286 (3rd Cir. 1983); Environmental Defense Fund, Inc. v. Lamphier, 714 F.2d 331, 338-39 (4th Cir. 1983); Diapulse, 457 F.2d at 28. Furthermore, violation of such statutes is presumed to cause public harm; the government need only establish that

defendants have violated the statute and there exists "some cognizable danger of recurrent violation." United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953); Roe v. Cheyenne Mountain Conference Resort, Inc., 124 F.3d 1221, 1230-31 (10th Cir. 1997); Lennen, 640 F.2d at 260; Diapulse, 457 F.2d at 28; United States v. 22 Rectangular & Cylindrical Finished Devices, 714 F. Supp. 1159, 1167 (D. Utah 1989)("[h]ere, it is sufficient to warrant an injunction under section 332(a) if it is established that the defendants violated section 331 and that such violations likely will continue").

Status Quo

10. In O Centro Espirita, the Court of Appeals rejected an "absolute" approach to defining the status quo, instead holding that "the definition of 'status quo' for injunction purposes depends very much on the facts of a particular case." O Centro Espirita, 342 F.3d at 1178. The status quo need not be the state of affairs immediately preceding litigation. Id.

11. The government contends that in this case, Congress established the status quo by outlawing the activities in which the defendants now engage. Unlike the facts of O Centro Espirita itself, which implicated two seemingly conflicting federal statues, Rx Depot's importation of prescription drugs clearly violates the law. The decision in SCFC ILC, Inc. v. Visa USA, Inc., 936 F.2d 1096 (10th Cir. 1991), cited by defendants, is

also distinguishable in that it involved a dispute between two private litigants. Id. at 1097-98. As set out above, the normal requirements applicable to private litigants do not apply where, as here, the government seeks to enforce a duly enacted statute designed to protect the public. By definition, such an action can be brought only after the law is broken; where the violation is obvious, preserving the "status quo" as defendants define it would mean protecting illegal activity.

12. The government has conclusively shown that the relevant statutory provisions explicitly prohibit exactly what the defendants' continue to do. Weighing the particular facts of this case, as required by O Centro Espirita, the Court finds that the defendants altered the status quo when they began to build a nationwide business based on violating the law.[2]

13. Even if the government's motion were construed as an attempt to change the status quo, the relevant preliminary injunction factors as outlined below weigh heavily and compellingly in the government's favor. Applying the heightened standard in this case, therefore, would not change the result. O Centro Espirita at 1177-78, n.3.

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[2]Contrary to the defendants' assertion, the government did not "admit" that its proposed injunction would alter the status quo. The government has maintained that the proposed injunction would force the defendants' stores to close, thereby preserving the status quo created by Congress.

Preliminary Injunction Factors

14. Regarding the first factor, the defendants openly and notoriously violate the law. As previously noted, the defendants admit the relevant facts. Defendants advertise and handle orders for Canadian pharmacies and are remunerated for their efforts. Their actions encouraging and facilitating the illegal importation of drugs constitute the requisite "causing" under 21 U.S.C. § 331. United States v. Dotterweich, 320 U.S. 277, 284 (1943); United States v. Brittain, 931 F.2d 1413, 1419 (10th Cir. 1991) (holding liable under FDCA those who have a "responsible share in the furtherance of the transaction which the statute outlaws"). The government has established more than a substantial likelihood that it will succeed on the merits.

15. The evidence conclusively demonstrates that the defendants' violations will continue absent an injunction by this Court. Defendant Moore admitted that his storefronts would remain open absent a court order. Even aside from this admission, the probability of future violations may be inferred from past unlawful conduct. Odessa Union, 833 F.2d at 176; Commodity Futures Trading Comm'n v. British American Commodity Options Corp., 560 F.2d 135, 144 (2d Cir. 1977).

16. As discussed above, weighing the respective harms to the parties is not required here; even were such a test necessary, the defendants would suffer only the "harm" of being

ordered to refrain from illegal activity. Despite the defendants' assertions to the contrary, the FDCA is a constitutional exercise of the commerce power. United States v. Walsh, 331 U.S. 432, 434 (1947). The defendants have no vested interest in an illegal business activity. Diapulse, 457 F.2d at 29; U.S. v. Articles of Drug, 825 F.2d 1238, 1248 (8th Cir. 1987).

17. As stated above, the government need only show the defendants' violations of the FDCA in order to prove public harm. "The passage of the statute is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained." Diapulse, 457 F.2d at 28 (citing United States v. City and County of San Francisco, 310 U.S. 16 (1940)); see also Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (affirming public interest in the "faithful application of the laws"); Bioganic Safety Brands, Inc. v. Ament, 174 F. Supp.2d 1168 (D. Colo. 2001) (holding in a preemption case that fourth factor is satisfied where Congress has determined the public interest). Here, Congress explicitly found that the unrestricted reimportation of U.S.-manufactured drugs created "an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers." PL 100-293, Sec. 2 ("Findings"), April 22, 1988 (available on Westlaw at 102 Stat 95). Defendants' contention that FDA's enforcement action

would not actually protect the public from anything is not supported by the record and, moreover, irrelevant. See United States v. Undetermined No. of Unlabeled Cases, 21 F.3d 1026, 1028 (10th Cir. 1994) (role of court is to determine whether law empowers FDA to act, not the efficacy of those actions). Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for the courts to enforce them when asked. TVA v. Hill, 437 U.S. 153, 194 (1978).

18. The Court recognizes that individual customers of the defendants believe that they benefit from the low prescription drug prices offered by Rx Depot/Rx Canada. However, the defendants are able to offer such low prices only because they facilitate illegal activity determined by Congress to harm the public interest. The legislature, not this Court, is the best forum for weighing all of the costs and benefits of the national statutory scheme regulating prescription drug importation. United States v. 9/1 Kg. Containers, More or Less, of an Article of Drug for Veterinary Use, 854 F.2d 173, 179 (7th Cir. 1988) ("Subjects such as these are for Congress and the FDA to consider. Judges' role is to decipher and enforce the existing scheme, whatever they think of its wisdom.").

Selective Enforcement Claim

19. Defendants' claim of unconstitutionally selective enforcement by FDA is unavailing. FDA's personal importation

policy, cited by defendants, outlines specific circumstances in which the agency generally will decline to prosecute the illegal importation of small quantities of prescription drugs by individuals. By its express terms, this policy of enforcement discretion does not apply to commercial operations such as Rx Depot/Rx Canada. See Gov't. Ex. 21.

20. Moreover, the Supreme Court has held that "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." Heckler v. Cheney, 470 U.S. 821, 831 (1985). To prevail on a claim of selective prosecution, therefore, the defendants must show that others similarly situated have not been subject to enforcement proceedings by the government, and that there was a constitutionally impermissible basis for the decision to institute enforcement action against the defendants such as race, religion, or other arbitrary classification. United States v. Armstrong, 517 U.S. 456, 464 (1996) (citing Oyler v. Boles, 368 U.S. 448, 456 (1962)); Wayte v. United States, 470 U.S. 598, 608 (1985). Defendants have made no such showing here. Instead, the defendants point to FDA's failure to prosecute all individuals who cross the Canadian border on their own to buy drugs. Defendants claim that this fact evidences some vague policy of "geographical" discrimination. It is reasonable, however, for FDA to marshal its limited resources against large-scale, commercial operations

such as Rx Depot/Rx Canada rather than small-scale, individual violators.

21. The purported "Congressional intent" referred to by defense counsel during the hearing represents a limited reading of the Medicine Equity and Drug Safety Act of 2000 (the "MEDS Act"). Congress conditioned the implementation of the MEDS Act on a determination by the Secretary of Health and Human Services that the envisioned new system would pose no additional health risks to U.S. consumers, and that it would result in significant cost savings to the American public. 21 U.S.C. § 384(l). The current and previous HHS secretaries have not made such a determination. Gov't. Ex. 22; Trans. at 133, 139.

22. Defendants' remaining claims, mentioned in their arguments before this Court and in their pleadings, similarly do not justify affirmative relief nor do they override the government's interest in enforcing the law. The Privileges and Immunities Clause does not apply here; in any event, the defendants have not shown that they have a fundamental right to facilitate illegal prescription drug importation. See Supreme Court of New Hampshire v. Piper, 470 U.S. 274, 279 (1985). Likewise, the facilitation of such imports, even to the extent it involves "speech," is not protected by the First Amendment. See United States v. Pinelli, 890 F.2d 1461, 1472 (10th Cir. 1989) (illegal conduct not protected simply because it involves speech) (citing Giboney v. Empire Storage & Ice Co., 336 U.S. 490, 502

(1949)); Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376, 389 (1973)(any First Amendment interest in advertising a commercial transaction is "altogether absent when the commercial activity itself is illegal and the restriction on advertising is incidental to a valid limitation on economic activity."). Finally, the North American Free Trade Agreement, as defendants conceded at the hearing, provides no remedy to private citizens. 19 U.S.C. § 3312(c); Trans. at 13.

Conclusion

23. FDA warned the defendants that their violations would subject them to enforcement action. Notwithstanding this warning, the defendants failed to comply with the FDCA; in fact, they expanded their operations. Unless restrained by order of this Court, the defendants will continue to violate 21 U.S.C. §§ 331(d) and (t).

24. Plaintiff is entitled to a preliminary injunction.

25. For the same reasons described herein, the defendants are not entitled to a preliminary injunction.

26. Any proposed Finding of Fact more appropriately considered a Conclusion of Law is submitted as such.

Respectfully submitted,

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